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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,734	04/21/2004	Diane T. Stephenson	PHA 42641.1 (01382/2/US)	4758

321 7590 07/30/2007

SENNIGER POWERS
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
WANG, SHENGJUN	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
07/30/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No.	Applicant(s)	
	10/828,734	STEPHENSON ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-38 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujimoto et al. (US 6,291,523), Carter et al. (US 6,034,256, IDS), Talley et al. (US 5,466,823, 5,633,272, 5932,598, IDS), Graneto (US 5,521,207, IDS), Ducharme et al. (US 5,474,995), Dube et al. (WO 98/03484, IDS), Black et al. (WO 00/24719, IDS), Olesen et al. (WO 99/25347), Kem et al. (US 6,077,680), and Arch et al. (WO 94/13272).

3. The claims are directed to concomitant administration of a COX-2 selective inhibitor and a potassium ion channel modulator for the treatment of pain, or inflammation related diseases.

4. Fujimoto et al. (US 6,291,523), Carter et al. (US 6,034,256, IDS), Talley et al. (US 5,466,823, 5,633,272, 5932,598, IDS), Graneto (US 5,521,207, IDS), Ducharme et al. (US 5,474,995, IDS), Dube et al. (WO 98/03484, IDS), and Black et al. (WO 00/24719, IDS) as whole teaches that selective COX-2 inhibitors in general, and the recited compounds herein in particular, are known to be useful for treatment of pain, inflammation, or inflammation mediated diseases, such as arthritis, inflammatory bowel disease, irritable bowel syndrome, Cohn's disease. See, e.g., US 5,932,598, col. 2, line 63 to col. 3, line 12; US 6,034,256 col. 3, line 58 to col. 4, line 48. Those compounds may be formulated into a variety of dosage forms suitable for

oral, parenteral, or topical administration. See, columns 81-83 in 5,932,598; col. 14, line 1, to col. 15, line 10. Specifically, Fujimoto et al. ('523), teach the phenylacetic acid compounds as recited in claim 22-23, and 34 as selected COX-2 inhibitors, See, the abstract, col. 2, lines 1-25, and the claims, claim 26 in particular. Carter et al. teaches the benzopyran compounds (claims 10-11 and 33) as selective COX-2 inhibitors, see, the abstract, col. 3, lines 58 to col. 4, line 42. Talley et al. teach celecoxib (5,466,823, col. 53, line 15), valdecoxib (5, 633,272, col. 22), and parecoxib (5,932,598, col. 49) as selective COX-2 inhibitors; Ducharme et al. (5,474,995, col. 27, compound 23) teach Refocoxib; Dube et al. (WO 98/03484, page 30) teach etoricoxib; Graneto (US 5,521,207, col. 43, example 1) teaches Darecoxib; and Black et al. teaches the compound recited in claim 32. See, particularly, page 79, lines 28-29.

5. Olesen et al., Kem et al. and Arch et al. teaches that potassium channel modulators, such as nicorandil, clotrimazole and Stichodactyla toxin, are known to be useful as analgesics and as anti-inflammatory agents. Specifically, Arch reveals that potassium channel activator, such as nicoranil, are known to be effective analgesics. See, particularly, the abstract and claim 14; Olesen et al. teaches that potassium channel modulators, such as clotrimazole, are useful for treatment of arthritis and Chron's disease; See, particularly, the abstract, page 11, line 18, page 20, line 9-15. Kem et al. also teach that Stichodactyla toxin are useful for treatment of various autoimmune diseases, including rheumatoid arthritis, Chron's disease. See, particularly, the abstract, and the claims.

6. The references do not teach expressly the concomitant administration of selective COX-2 inhibitor and potassium channel blocker for treatment of pain, inflammation or inflammation mediated diseases.

However, it would have been obvious concomitantly administer a COX-2 selective inhibitor and a potassium channel blocker, such as nicorandil, clotrimazole and Stichodactyla toxin, to a patients in need of treatment of pain, inflammation, or inflammation mediated disease because both the selective COX-2 inhibitors and sodium channel blockers are known to be useful for treatment of pain, inflammation and inflammation mediated diseases.

It is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art. See In re Kerkhoven, 205 USPQ 1069.

The evidence presented by the reference shows that the subject matter as claimed is a combination of known components selected for their known properties as analgesics and/or anti-inflammatory agent. A claim which unites elements with no change in their respective functions to yield a predictable result is not patentable in the absence of secondary considerations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617

S. Wang